FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Meeting of the Pulmonary-Allergy Drugs Advisory Committee (PADAC)

FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503), Silver Spring, MD

April 17, 2013

DRAFT QUESTIONS

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1. **DISCUSSION:** Discuss the efficacy data for fluticasone furoate/vilanterol (FF/VI) 100/25 mcg once daily in comparison to the data for VI 25 mcg alone in support of the two proposed indications:
    - the long-term, maintenance treatment of airflow obstruction
    - the reduction of chronic obstructive pulmonary disease (COPD) exacerbations

2. **VOTE:** Do the efficacy data provide substantial evidence of a clinically meaningful benefit for FF/VI 100/25 mcg once daily for the long-term, maintenance treatment of airflow obstruction in COPD?
    - *If not, what further data should be obtained?*

3. **VOTE:** Do the efficacy data provide substantial evidence of a clinically meaningful benefit for FF/VI 100/25 mcg once daily for the reduction of COPD exacerbations?
    - *If not, what further data should be obtained?*

4. **DISCUSSION:** Discuss the overall safety profile of FF/VI 100/25 mcg once daily.

5. **VOTE:** Has the safety of FF/VI 100/25 mcg once daily in COPD been adequately demonstrated for the proposed indications?
    - *If not, what further data should be obtained?*

6. **VOTE:** Do the efficacy and safety data provide substantial evidence to support approval of FF/VI 100/25 mcg once daily for the long-term, maintenance treatment of airflow obstruction in COPD?
    - *If not, what further data should be obtained?*

7. **VOTE:** Do the efficacy and safety data provide substantial evidence to support approval of FF/VI 100/25 mcg once daily for the reduction of COPD exacerbations?
    - *If not, what further data should be obtained?*